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MARTIN & FERRARO, LLP
1925 Century Park East, 17th Floor
Los Angeles, California 90067Telephone
(310) 286-9800Facsimile
(310) 286-2795

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TO:

Name: Mail Stop AMENDMENT
Art Unit 3732/Examiner Pedro Philogene

Firm: U.S. Patent & Trademark Office

Fax No.: 703-872-9306

Subject: U.S. Patent Application No. 09/768,991

Gary K. Michelson

Filed: January 23, 2001

INTERBODY SPINAL IMPLANT WITH TRAILING
END ADAPTED TO RECEIVE BONE SCREWS
(as amended)

Attorney Docket No. 101.0101-00000

Customer No. 22882

Confirmation No.: 4198

FROM:

Name: Amedeo F. Ferraro

Phone No.: 310-286-9800

No. of Pages (including this): 9

Date: January 3, 2005

Confirmation Copy to Follow: NO

Message:

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

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FORM PTO-1083

Attorney Docket No.: 101.0101-00000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson, M.D.

Serial No: 09/768,991

Filed: January 23, 2001

For: INTERBODY SPINAL IMPLANT WITH
TRAILING END ADAPTED TO
RECEIVE BONE SCREWS (as
amended)

Confirmation No.: 4198

Art Unit: 3732

Examiner: Pedro Philogene

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is a reply to the Office Action dated July 2, 2004 in the above-identified application.

- ☐ No additional fee is required.
- ☒ Applicant hereby requests a three-month extension of time to respond to the above office action.
- ☒ The total amount of \$1,020.00 to cover the three-month extension fee is to be charged to Deposit Account No. 50-1066.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. A copy of this sheet is enclosed.
- ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
- ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

Date: January 3, 2005

By: Amedeo F. Ferraro
Registration No. 37,1291557 Lake O'Pineas Street, NE
Hartville, Ohio 44632
Telephone: 330-877-0700
Facsimile: 330-877-2030

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PATENT
Attorney Docket No. 101.0101-00000
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Confirmation No.: 4198
Gary K. Michelson, M.D.)	
Serial No.: 09/768,991)	Group Art Unit: 3732
Filed: January 23, 2001)	Examiner: P. Philogene
For: INTERBODY SPINAL IMPLANT)	
WITH TRAILING END ADAPTED)	
TO RECEIVE BONE SCREWS)	
(as amended))	

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY TO OFFICE ACTION

In reply to the Office Action dated July 2, 2004, the period for reply having been extended for three (3) months by a request for extension and fee payment filed concurrently herewith, the following remarks are submitted as follows:

In the Office Action, the Examiner rejected claims 1-14, 18-31, 33, 34, 62-71, 81-91, 94-109, 112-150, and 195-204 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,342,074 to Simpson ("Simpson") in view of U.S. Patent No. 6,214,005 to Benzel ("Benzel"). Applicant respectfully traverses the rejection.

Simpson teaches an artificial spinal implant that is adapted to be held in place by bone screws passing through the trailing end of the implant. (Simpson, col. 7, lines 56-60; Fig. 3).

Benzel discloses a spinal column retaining apparatus including a pair of rods (12, 14) and plates (30, 32) which engage the rods along vertical axis A of the human body.

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Each rod has a length "which is sufficient to enable the rods to span at least the two vertebrae V1 and V2." (Benzel, col. 2, lines 26-35, 54, and 55 and Fig. 1). Plates 30, 32 have inner side surfaces (64, 164) adapted to engage the anterior surface of the vertebrae. (Benzel, col. 3, lines 1-5; and col. 6, lines 6-11). Each of the plates of Benzel does not have a trailing end with an upper edge and a lower edge having maximum height therebetween as measured along the longitudinal axis of the spine that is adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space as recited in Applicant's claimed invention.

A. Many of the Independent Claims Recite Features Not Taught or Suggested by Simpson and Benzel.

Applicant submits that independent claims 1, 62, 81, and 100 each recite features not taught or suggested by Simpson and Benzel whether alone or when properly combined. Independent claim 1 recites a spinal implant with a leading end and a trailing end opposite the leading end, the trailing end having upper and lower edges and a plurality of bone screw receiving holes, at least one of the bone screw receiving holes being adapted to permit the trailing end of a bone screw to "protrude beyond said one of said edges of said implant and overlie at least in part one of the adjacent vertebral bodies." No such structure is taught, disclosed, or suggested by Simpson and Benzel whether alone or when properly combined. For the apparatus disclosed by Benzel in particular, each plate 30a does not have upper and lower edges that are adapted to be oriented toward the adjacent vertebral bodies. At least one of the edges is positioned completely outside of the disc space and is therefore not oriented toward any vertebral body. (See, e.g., Benzel, Fig. 9). To the extent that the screw in the Benzel device extends beyond the edge, it extends into the disc space and does not overlie one of the adjacent vertebral bodies as recited in claim 1.

Independent claim 62 recites "at least one of said bone screw receiving holes interrupting only said upper edge of said trailing end, and another one of said bone screw receiving holes interrupting only said lower edge of said trailing end." No such structure is taught, disclosed, or suggested by Simpson and Benzel whether alone or

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when properly combined. For the apparatus disclosed by Benzel, only the interior edge between the upper and lower portions of the apparatus is interrupted by a bone screw receiving hole. In particular, Figs. 2 and 9 of Benzel show that the upper and lower portions of the apparatus are not interrupted by any bone screw receiving holes.

Independent claim 81 recites at least one of a plurality of bone screw receiving holes passing through the exterior surface and one of the upper and lower edges of the trailing end "so as to permit the bone screw to protrude over one of said edges within a plane of said trailing end." No such structure is taught, disclosed, or suggested by Simpson and Benzel whether alone or when properly combined. For the apparatus disclosed by Benzel in particular, Figs. 2 and 9 show that the upper and lower portions of the apparatus do not permit a bone screw to protrude over one of the portions within a plane of the trailing end.

Independent claim 100 recites a trailing end having an outer perimeter with an upper edge and a lower edge, each of the upper and lower edges of the outer perimeter having a single gap therein for permitting a portion of a bone screw to protrude over the respective edge of the perimeter. No such structure is taught, disclosed, or suggested by Simpson and Benzel whether alone or when properly combined. For the apparatus disclosed by Benzel, only the interior edge between the upper and lower portions of the apparatus is interrupted by a bone screw receiving hole. In particular, Figs. 2 and 9 of Benzel show that the upper and lower portions of the apparatus are not interrupted by any bone screw receiving holes.

B. The Combination of Simpson and Benzel is Improper Because the Proposed Modification Renders the Combination Unsuitable For Its Intended Purpose.

Simpson teaches screw holes that angle the bone screw away from the longitudinal axis of the implant at each of the top and bottom surfaces of the implant. (See, e.g., Simpson, Fig. 2). Benzel teaches screw holes that position bone screws either parallel to or at an angle toward the longitudinal axis of the plate. (See, e.g., Benzel, Figs. 2 and 10). In Benzel, bone screws (40, 42) passing through the lower edge of the trailing end of plate (30) are angled toward the upper surface of plate (30)

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and the bone screws (44, 46) passing through the upper edge of the trailing end of plate (32) are angled toward the lower surface of plate (32). Modifying the screw holes of Simpson as taught by Benzel would render the Simpson device unsuitable for its intended purpose. If so modified, positioning bone screws parallel to or at an angle toward the longitudinal axis of the implant of Simpson would fail to provide adequate anchoring of the implant to the adjacent vertebral bodies in a manner consistent with the teachings of Simpson as the bone screws at the lower edge would be angled upward and the bone screws at the upper edge would be angled downward. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-131, col. 2 (May 2004)). (See MPEP § 2143.01, "The Proposed Modification Cannot Change the Principle of Operation of a Reference," page 2100-132, col. 1 (May 2004)). Accordingly, Applicant submits that the rejection is improper and must be withdrawn.

The Examiner rejected claims 15, 16, 35-54, 56-61, 72-80, 92, 93, 110, 111, and 152-194 under 35 U.S.C. § 103(a) as being unpatentable over Simpson in view of Benzel and U.S. Patent No. 6,629,998 to Liu. Applicant respectfully traverses the Examiner's rejection.

A. The Combination of Simpson, Benzel, and Liu is Improper Because Simpson and Liu teach away from one another.

Applicant submits that the proposed combination of Simpson and Benzel with Liu is untenable because Simpson teaches away from the apparatus of Liu. Liu teaches that it is "preferable" to have a filling body 100 configured to receive a bone nail 200 that allows "a greater micromotion between the filling body and the bone nail (the vertebrae)." (Liu, col. 2, lines 52-55 and Fig. 1). Simpson teaches that "[a]nterior interbody fusion ... is likely to achieve unsatisfactory results if relative movement takes place between the adjacent vertebrae while fusion is underway. If relative movement of adjacent vertebral bodies takes place while fusion is underway, this will, as a minimum, slow the rate of fusion, and can prevent acceptable fusion results from being achieved" as well as cause "significant continued back pain after surgery." (Simpson, col. 2, lines

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33-44). (See MPEP § 2143.01, "The Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004); and MPEP § 2145(X)(D)(2), "References Cannot Be Combined Where Reference Teaches Away from Their Combination," page 2100-132, col. 1 (May 2004)). Accordingly, Applicant submits that the rejection is improper and must be withdrawn.

B. The proposed combination still does not yield Applicant's claimed invention.

Independent claim 44 recites a trailing end having a maximum height, the trailing end "being adapted to receive at least a portion of a bone screw passing therein that extends beyond said maximum height immediately adjacent thereto" and overlies at least in part one of the adjacent vertebral bodies. No such structure is taught, disclosed, or suggested by Simpson, Benzel, and Liu whether alone or when properly combined. The trailing ends disclosed by Simpson, Benzel, and Liu receive bone screws having portions immediately adjacent the trailing end that are within the maximum height of the respective trailing end. (See, e.g., Simpson, Fig. 2; and Liu, Fig. 2). For the apparatus disclosed by Benzel in particular, Figs. 2 and 9 show that the portions of fasteners 38, 40, and 42 immediately adjacent the trailing end are all well within the maximum height of the trailing end of the apparatus. To the extent that the screw in the Benzel device extends beyond the edge, it extends into the disc space and does not overlie one of the adjacent vertebral bodies as recited in claim 44.

Applicant submits that Independent claims 1, 26, 44, 62, 81, and 100 are allowable and that dependent claims 2-16, 18-25, 27-31, 33-43, 45-54, 56-61, 63-80, 82-99, 101-150, and 152-204 are allowable at least because they depend from an allowable independent claim, or claims dependent therefrom. Applicant submits that the rejections of claims 1-16, 18-31, 33-54, 56-150, and 152-204 over the art of record have been overcome.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

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To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted

MARTIN & FERRARO, LLP

Dated: January 3, 2005

By: 

Amedeo F. Ferraro
Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030